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In re Application of CLAYTON et al
Application No.: 10/561,713
PCT No.: PCT/GB04/02707
Int Filing: 23 June 2004
Priority date: 23 June 2004
Attorney docket No.: 5585-72843-01
For: INFFLAMOTORY DISEASE TREATMENT

WITHOUT PREJUDICE

29th April 2008

Dear Ms Kratz

Further to your letter dated 15 April 2008. The document I submitted is accurate and reflects the true inventors of the patent. Diane Clayton was added as an additional inventor prior to filing. I enclose a copy of internal disclosure document from Advanced BioNutrition Corporation (ABN Corp) detailing the named inventors at time of invention. There are a number of other documents that support this.

ABN Corp, and I assume therefore their counsel of record, are fully aware of my objections and have failed to offer me a reasonable contractual arrangement to commercialise this patent, and thus be part of the application process. Counsel of Record does not act on my behalf, counsel of record acts solely for ABN Corp.

I assume the Patent Office was unaware of this discrepancy, but can now take all appropriate steps to ascertain the correct position. This declaration I believe is therefore honest, meets all requirements.

Yours truly,


Rebecca Rutter

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Patent Disclosure #:

Brief Title: DHA and astaxanthin work in combination as a post-trauma healing to reduce inflammation and length of healing time

Inventor(s): (full name and home address) Rebecca Rutter, 13 Willingdon Way, Lower Willingdon, Eastbourne, East Sussex, BN22 0NJ

Summary of Invention: DHA and astaxanthin may work synergistically to reduce inflammation and speed healing of wounds and traumas. (There is of course the presence of yeast in the product, which might play a significant role as well. When we begin testing the components of the product individually we may be able to clarify this further).

Prior Art:

DHA has been recognized as an essential fatty acid (EFA) for many years. Fish oils, specifically cod liver oil have historically been used to ease inflammatory conditions - gingivitis, enteritis, conjunctivitis etc. Research has showed an antioxidant effect of algal astaxanthin extract in cancer cells, reproduction, enhanced immune response and pre-weaning growth in a range of organisms. It has also been shown that animals consuming other organisms with high levels of astaxanthin benefit from the protective properties of this nutrient. In humans the anti-inflammatory effect of these compounds has been postulated as a basis for supplementing patients' diet with these compounds.

US patent number 6,265,450 details the use of astaxanthin as an anti-stress compound in human food.
US patent number 6,440,470 details the use of astaxanthin in human medicinal use.

Description & Examples:

Historically cod liver oil has been used to ease stiffness in equines as well as providing a shine to the coat - e.g. Codliverine supplements produced by Battle Hayward and Bower. DHA has a long and scientifically sound history of use in human foods, and as a supplement for other species to improve age related deterioration.

Many studies show the use of multi-component EFA sources (e.g. cod liver oil, flax oil, perma based chondroitin and glucosamine products) as being beneficial for a variety of species.

Little work has been done on the use of DHA as the sole component despite information indicating an adverse effect by EPA due to an inhibitory response.

There are few studies in any species showing the effect of astaxanthin either alone or in combination with other compounds.

There are no current references for the use of DHA and astaxanthin in combination to combat inflammation and aid healing in any species or model systems.

Chronology of Invention:

1. Date Idea first thought up - August 2002
2. Location/date of first written information - report issued to ABN Corporation following case analysis 27/09/02

Market Potential:

1. Existing products - Fish and flax derived oils. Glucosamine and chondroitin based products e.g. Cortaflex; herbal products to improve specific disorders e.g. GroWell Feeds ImmuneAid, Devils Claw, No Bute. Phenylbutazone, chemical anti-inflammatory commonly given to equines for a variety of reasons.

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Inventor(s): (Signature & Date) Rebecca Rutter 14/3/03

Witness: [Signature] 14.3.03

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2. Advantage/need – many horses suffer joint problems and health problems following injury. Some of these effects can be long standing and can lead to a foreshortening of active life / use, this is especially common in those used for high-impact sports e.g. jumping, endurance riding, dressage, flat racing. Use of natural products have fewer side effects and are of higher perceived value than manufactured chemicals to achieve healing time. Prevention of injury and speed of recovery is important to commercial use of horses (e.g. racing, show jumping etc) as well as to companion animals. Most long term treatments for inflammatory related conditions are prohibited by the Jockey Clubs, FEI (International Equestrian Federation) and national regulatory bodies. There are severe penalties for the use of any such compounds, and testing is strictly maintained.
3. Competitors – currently flexion and joint health products containing fish oil and flax oil e.g. NAF Joint Flex, Codliline, Solvitax Super oils. Sodium hyaluronate (Bayer Vet Care), phenylbutazone, Cortaflex.
4. Rheumatoid arthritis is characterized by inflammation, usually symmetrical, of the peripheral joints, possibly resulting in the progressive destruction of the joints and surrounding structures. Rheumatoid arthritis is an auto-immune disease caused mainly by increased T-cell Cytokines such as IL-1 and TNF, which subsequently release *prostaglandins* and *Thromboxane A₂*. It has been shown that increased consumption of fatty acids, namely Omega-3, has a beneficial effect on human patients with rheumatoid arthritis. The oils have been shown to contain *eicosanoids* that inhibit the formation of series-2 *prostanoids* and series-4 *Leukotrienes*, which themselves result in increased consumption of *corticosteroids* and non-steroid anti-inflammatory drugs (NSAIDs). Current equine treatment is long term phenylbutazone, giving rise to long term liver, kidney and retinal disorders.

Literature Cited:

1. Veterinary Medical Uses And Sources of Omega-3 Fatty Acids John E. DeGroot, DVM, Veterinary Forum, May 1998
2. Healing Fats For Animals (and us) © by Udo Erasmus
3. NM Lyons and NM O'Brien Modulatory effects of an algal extract containing astaxanthin on UVA-irradiated cells in culture. J Dermatol Sci. 2002 Oct;30(1):73-84.
4. Hansen KB, Tauson AH, Inborr J. Effect of supplementation with the antioxidant astaxanthin on reproduction, pre-weaning growth performance of kits and daily milk intake in mink. J Reprod Fertil Suppl. 2001;57:331-4. PMID: 11787170 [PubMed - indexed for MEDLINE]
5. Calder PC. Dietary modification of inflammation with lipids. Institute of Human Nutrition, University of Southampton, Bassett Crescent East, UK. pcc@soton.ac.uk
6. Huang, M. and Craig-Schmidt, M.C. (1996) Arachidonate and docosahexaenoate added to infant formula influence fatty acid composition and subsequent eicosanoid production in neonatal pigs. Journal of Nutrition 126:9 2199-2208
7. Enser M., Richardson R.I., Nute G.R., Fisher A.V., Scollan N.D., Wood J.D., 2001, Effect of red and white clover on beef meat quality, *The Proceedings of the British Society of Animal Science* pp75.

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Inventor(s) : (Signature & Date)

Hunter

14/3/03

Witness :

D. E. Clark

14.3.03